

1 REMARKS

2 Status of the Claims

3 Claims 1, 2, 4-27 and 52-58 remain pending in the present application, Claims 3 and 28-51
4 having been previously canceled, and Claims 1, 2, 14, 21, 23, 25, 26, 52-54, 57, and 58 having been
5 amended as noted above, in order to more clearly define the novel technology.

6 Brief Summary of Telephone Interview

7 On May 14, 2008, applicants' attorney conducted a telephone interview to discuss the Office Action
8 with Examiner Utama and Primary Examiner Mosser. With respect to the topic of applicants' empirical
9 studies in the specification, Examiner Utama and Primary Examiner Mosser explained that they are looking
10 for comparative studies or objective evidence, such as lab results, to support applicants' assertions. They
11 also explained that these studies needed to be submitted in a separate Declaration.

12 The reasons why one of ordinary skill in the art would be led to modify the references to read
13 on the claimed subject matter was also briefly discussed.

14 With respect to the topic of the rejection of Claims 14-17, 25, and Claims 54-58 as being treated
15 as product-by-process claims, Examiner Utama and Primary Examiner Mosser explained that use of
16 the term "formed" in these claims is problematic, and that a term such as "within" would likely be
17 sufficient to clarify that these claims are not product-by-process claims.

18 Applicants' attorney would like to thank Examiner Utama and Primary Examiner Mosser for their
19 time and willingness to discuss these issues during the Telephone Interview. No decision regarding
20 patentability of any of the claims was reached during the discussion, but it appears that Examiner Utama and
21 applicants' attorney have a clearer understanding of each other's position as a result of discussion during the
22 Interview.

23 Claims Rejected Under 35 U.S.C. § 103(a)

24 Claims 1, 2, 4-27, and 52-58 have been rejected under 35 U.S.C. § 103(a) as being
25 unpatentable over U.S. Patent No. 4,708,836 (Gain et al. - hereinafter referred to as "Gain") in view
26 of NPL #1, "Infant Skull Model and Sculpted Head" (retrieved on Jun 09, 2002) and further in view
27 of U.S. Patent No. 2003/0208 (Cecchi). Applicants respectfully disagree with the above rejections
28 for at least the following reasons, particularly, in view of the amendments made to the claims in this
29 response.
30

1 In the interest of reducing the complexity of the issues for the Examiner to consider in this
2 response, the following discussion focuses on independent Claims 1, 21, 27, 52-54, and 57-58. The
3 patentability of each remaining dependent claim is not necessarily separately addressed in detail.
4 However, applicants' decision not to discuss the differences between the cited art and each dependent
5 claim should not be considered as an admission that applicants concur with the Examiner's
6 conclusion that these dependent claims are not patentable over the disclosure in the cited references.
7 Similarly, applicants' decision not to discuss differences between the prior art and every claim
8 element, or every comment made by the Examiner, should not be considered as an admission that
9 applicants concur with the Examiner's interpretation and assertions regarding those claims. Indeed,
10 applicants believe that all of the dependent claims patentably distinguish over the references cited. In
11 any event, a specific traverse of the rejection of each dependent claim is not required, since
12 dependent claims are patentable for at least the same reasons as the independent claims from which
13 the dependent claims ultimately depend.

14 Patentability of Independent Claim 1

15 Claim 1 has been amended to now recite, "*means for preventing tactile detection of a*
16 *simulated patent skull suture in the model, while enabling the simulated patent skull suture to be*
17 *visually detected based upon an appearance of the simulated patent skull suture in an ultrasound*
18 *image of said model, said means comprising a second material that is selected to have an*
19 *echogenicity substantially different than an echogenicity of said first material, such that each*
20 *simulated patent skull suture can be readily distinguished in an ultrasound image of said model.*"

21 The Examiner has indicated that providing a model with openings that simulate the patent sutures in
22 an infant's skull is known based on the photo shown in the first NPL reference, and that it would
23 have been obvious to manipulate the density of the second material as taught by Cecchi to achieve the
24 correct echogenic properties. However, none of the cited references teach or suggest that such a
25 second material should also be disposed within the openings of a model of a skull to prevent tactile
26 identification that an opening is disposed at a specific point on the model. The intention is that the
27 second material disposed in these openings instead be visually identified in the ultrasound image of
28 the model. This point is clearly made in applicants' specification in the paragraph starting at line 21
29 of page 11. Applicants have recited this function in a means plus function clause. Claim 2 further
30 explains that the second material at least partially filling the openings comprising the simulated

1 patent skull sutures comprises the means to accomplish the recited function. Since none of the
2 references teach or suggest use of a second material that performs both functions recited in the means
3 plus function clause of Claim 1 as amended, it will be evident that the claim is novel and non-obvious
4 over the cited art. Accordingly, the rejection of independent Claim 1 under 35 U.S.C. § 103(a)
5 should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 1 as
6 now amended.

7 Since dependent claims inherently include all of the recitation of the independent claims from
8 which they ultimately depend, for at least the same reasons as noted above in connection with
9 independent Claim 1, the rejection of dependent Claims 2 and 4 - 20 should also be withdrawn.

10 Patentability of Independent Claim 21

11 The Examiner rejected Claim 21 for reasons generally similar to those applied in rejecting
12 Claim 1. However, Claim 21 has been amended in the present response to recite, “*means for*
13 *selectively modifying the model between training sessions by enabling a filler material to be added*
14 *within at least one selected opening, the filler material having an echogenicity that is generally*
15 *similar to that of the portions of the model not corresponding to the simulated skull suture, so that*
16 *each opening in which the filler material is added simulates a fused skull suture in an ultrasonic*
17 *image, the model being modified between training sessions by removing the filler material from the at*
18 *least one opening and adding the filler material within at least one other different opening.*” None of
19 the art cited by the Examiner teaches or suggests filling an opening in a model of a skull with a filler
20 material that has an echogenicity that is generally similar to that of the other portions of the model,
21 where the model can be modified between training sessions by removing the filler material from at
22 least one opening and adding the filler material to a different opening. This approach is important so
23 that a student who has gone through one training session will not simply learn where the fused skull
24 suture is located on the model skull and be able to use that knowledge to indicate where the fused
25 skull suture is located in a subsequent training session. By providing means to change the location of
26 the simulated fused skull suture between training sessions, the usefulness of the model is greatly
27 enhanced. The functionality is not obvious in view of the art and is clearly supported in applicants’
28 specification at page 16, line 25. Accordingly, the rejection of independent Claim 21 under 35
29 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the
30 recitation of Claim 21 as amended.

1 Since dependent claims inherently include all of the recitation of the independent claims from
2 which they ultimately depend, for at least the same reasons as noted above in connection with
3 independent Claim 21, the rejection of dependent Claims 22-26 should also be withdrawn.

4 Patentability of Independent Claim 27

5 The Examiner has rejected Claim 27 over the teaching of Gain, and the infant skull model of
6 the NPL#1 reference. However, applicants respectfully disagree with this rejection for the following
7 reasons.

8 The Examiner appears to have overlooked a recitation in Claim 27 that is not taught or
9 suggested by the cited references. Specifically, Claim 27 recites, “*a substantially life size model of a*
10 *human head, said model including at least one simulated patent skull suture and at least one*
11 *simulated fused skull suture, an echogenicity of each simulated patent skull suture enabling the*
12 *simulated patent skull suture to be readily distinguishable from each simulated fused skull suture in*
13 *an ultrasound image of said model, such that each simulated patent skull suture will appear dark in*
14 *such an ultrasound image, and each simulated fused skull suture will appear bright in such an*
15 *ultrasound image.*” None of the references make any teaching or suggestion of including a simulated
16 fused skull suture in a model of a skull, which is not surprising, since that condition is NOT
17 considered a normal condition in an infant’s or child’s skull. Accordingly, it is further not surprising
18 that none of the references teach or suggest how such a simulated fused skull suture on a model of a
19 skull might be visually detected in an ultrasound image of an ultrasound trainer, as recited in this
20 claim. Thus, it should be apparent that Claim 27 is novel and non-obvious in view of the art cited.
21 For this reason, the rejection of independent Claim 27 under 35 U.S.C. § 103(a) should be withdrawn
22 because the cited art does not teach or suggest all of the recitation of Claim 27.

23 Patentability of Independent Claim 52

24 The Examiner rejected Claim 52 as obvious in view of Gain, since he concludes that using
25 materials of different density as taught by Gain would enable differences in the echogenicity of those
26 materials to be used to distinguish the first and second material in an ultrasound image of a model
27 and relies on the first NPL reference for teaching a model of a skull with patent openings. However,
28 applicants have amended Claim 52 to recite, “*at least one simulated patent skull suture that can be*
29 *selectively modified to appear as a simulated fused skull suture, a difference in echogenicity of each*
30 *simulated patent skull suture and each simulated fused skull suture enabling each simulated patent*

1 *skull suture to be readily distinguishable non suture portions of the model and from each simulated*
2 *fused suture in an ultrasound image of said model.”* The prior art references fail to teach or suggest a
3 simulated fused skull suture and do not in any way indicate how differences in echogenicity between
4 the simulated fused skull suture and the simulated patent skull suture might be used to distinguish
5 between the two in an ultrasound image. Accordingly, the rejection of independent Claim 52 under
6 35 U.S.C. § 103(a) should be withdrawn, because the cited art does not teach or suggest all of the
7 recitation of Claim 52 as now amended.

8 Patentability of Independent Claim 53

9 The Examiner again relies upon Gain and the first NPL reference for teaching the recitation of
10 Claim 53. But, since applicants have amended Claim 53 to recite, “*means for reversibly modifying*
11 *one or more selected simulated patent skull sutures to create one or more simulated fused skull*
12 *sutures that can readily be detected in an ultrasound image, wherein each simulated fused skull*
13 *suture will appear bright in the ultrasound image, like the portions of the model that are adjacent to*
14 *the simulated patent skull sutures,”* it will now be apparent that the claim recites a novel and non-
15 obvious approach that is not taught or suggested by the prior art references cited, since none of these
16 references even refer to including or detecting a simulated skull suture, and more importantly, do not
17 discuss any manner in which a simulated patent skull suture might be **reversibly** modified to produce
18 a simulated fused skull suture. Accordingly, the rejection of independent Claim 53 under 35 U.S.C. §
19 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of
20 Claim 53.

21 Patentability of Independent Claims 54 and 57

22 Claims 54 and 57 are rejected over a combination of Gain, the first NPL reference, and
23 Cecchi. The Examiner also rejects these two claims as being product by process claims, which are
24 still not patentable if the product is itself not patentable over the prior art. In response, applicants
25 have amended Claim 54 to recite, “*a third material being disposed within each opening*
26 *corresponding to a simulated fused skull structure, an echogenicity of the third material being*
27 *substantially distinguishable from the echogenicity of the second material, so that each simulated*
28 *fused skull suture can be readily distinguished from each simulated patent skull suture in an*
29 *ultrasound image of said model.”* None of the references teach a simulated fused skull suture or
30 teach or suggest that a third material disposed in an opening in a model of a skull is used for a

1 simulated fused skull suture. There is also no teaching or suggestion that the third material disposed
2 in an opening of a model of a skull might have an echogenicity that is readily distinguished from an
3 echogenicity of a second material used in the simulated patent skull sutures, so that the simulated
4 fused skull suture can be readily distinguished from each simulated patent skull suture in an
5 ultrasound image of the model. Accordingly, the rejection of independent Claim 54 under 35 U.S.C.
6 § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of
7 Claim 54.

8 Since dependent claims inherently include all of the recitation of the independent claims from
9 which they ultimately depend, for at least the same reasons as noted above in connection with
10 independent Claim 54, the rejection of dependent Claims 55 and 56 should also be withdrawn.

11 For similar reasons, Claim 57 is novel and non-obvious over the cited art. Accordingly, the
12 rejection of independent Claim 57 under 35 U.S.C. § 103(a) should be withdrawn because the cited
13 art does not teach or suggest all of the recitation of Claim 57.

14 Patentability of Independent Claim 58

15 Claim 58 was also rejected as a product-by-process claim. However, for much the same
16 reasons as discussed above, the amendment to Claim 58 makes it clear that it is not directed to a
17 product by process and is both novel and non-obvious over the cited art. Accordingly, the rejection
18 of independent Claim 58 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does
19 not teach or suggest all of the recitation of Claim 58.

20 Discussion of Product-by-Process Claim Rejection

21 Under the "Response to Arguments" section, as noted above, the Examiner applied a new
22 rationale of rejection to Claims 14-17 and 25 and Claims 54-58 and indicated that these claims are
23 treated as product-by-process claims. However, based on the interview summarized above,
24 Claims 14 and 54 have been amended to change the term "formed in" to "within," in regard to an
25 opening in the model, thereby making it clear that these claims are not product-by-process claims.
26 Applicants have also amended dependent Claim 2 to change "formed in" to "within" and have
27 amended Claim 26 such that it recites the term "disposed" instead of "formed." Furthermore,
28 Claims 14, 21, 25, 26, 54, 57 and 58 have been amended such that they recite that a material is
29 disposed in an opening as opposed to reciting an opening "being filled." These amendments are
30 made in an attempt to clarify that these claims are not product-by-process claims.

1 Conclusion

2 In consideration of the amendment to the claims and the Remarks set forth above, it is
3 applicants' position that all claims in the current application are patentable over the art of record.
4 The Examiner is thus requested to pass this case to issue without further delay. In the event that any
5 other issues remain, the Examiner is invited to telephone applicants' attorney at the number listed
6 below.

7 Respectfully submitted,

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